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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,190	02/28/2002	Pia M. Challita-Eid	511582003420	7796

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/087,190	CHALLITA-EID ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 83.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DAVID J. BLANCHARD
~~PATENT~~ EXAMINER
PRIMARY

Continuation of 11. does NOT place the application in condition for allowance because:
The rejection of claim 83 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated 121P1F1 transcript or transcripts that encode the protein of SEQ ID NO:2, does not reasonably provide enablement for: (i) any isolated 121P1F1 transcript variant that encodes a protein comprising at least one amino acid substitution, addition or deletion relative to SEQ ID NO:2 or the transcript variant of SEQ ID NO:5 is maintained.
The response filed 9/19/2007 states that while the present application does not investigate the biological function or role of 121P1F1 in living cells, applicant points out that 121P1F1 (SEQ ID NO:2) and its variants (i.e., SEQ ID NO:5) are enbaled as a marker for prostate cancer. Applicant states that the claimed 121P1F1 variant of SEQ ID NO:5 was identified by the use of EST data in an EST assembly approach and applicant refers to the specificatino as disclosing techniques for comfirming a splice variant, and when the genomic region to which 121P1F1 maps is modulated in a particular cancer, the splice variants of 121P1F1 are modulated as well. Applicant concludes that the specification thus provides splice variants of 121P1F1 that are structurally and functionally similar to 121P1F, which was shown in the specification to have a particular expression profile - will share this expression pattern and thus the splice variants can serve as tumor-associated markers/antigens. Further, applicant refers to the specification as providing ample disclosure with respect to expressing a 121P1F1 polypeptide in a host cell and methods of generating polyclonal and monoclonal antibodies to 121P1F1. Applicant states that Figures 13-14 show that a polyclonal antibody raised against the full-length 121P1F1 showed strong reactivity to variants of 121P1F1 in a number of cancer cell lines and thus, applicants have demonstarted that variants of 121P1F1 are expressed in cancer cell lines and the variants are useful as diagnostics. Applicants arguments have been fully considered but are not found persuasive. The examiner agrees that 121P1F1 (SEQ ID NO:2) is enabled as a marker for prostate cancer, however, the examiner maintains that the specification lacks adequate enablement regarding 121P1F1 variants, inclusive to SEQ ID NO:5 because there is insufficient guidance and direction as it pertains to the 121P1F1 variant of SEQ ID NO:5, and there is no evidence that SEQ ID NO:5 is differentially expressed in prostate cancer realtive to healthy prostate. Applicants' assertion that the specification provides splice variants of 121P1F1 that are structurally and fucntionally similar to 121P1F1 based on the disclosure of techniques for confriming a slice variant and mapping 121P1F1 to a genomic region modulated by a particular cancer is not found persuasive because 121P1F1 nor any splice variants have been mapped to a genomic region associated with cancer, and the description of methods for determining whether a splice variant possesses a certain desired characteristic, these descriptions, without more precise guidelines, amount to little more than "a starting point, a direction for further research." Genentech, 108 F.3d at 1366. See also Calgene, 188 F.3d at 1374 ("the teachings set forth in the specification provide no more than a 'plan' or 'invitation' for those of skill in the art to experiment practicing [the claimed invention]; they do not provide sufficient guidance or specificity as to how to execute that plan"); National Recovery Technologies, 166 F.3d at 1198 (stating that patent-in-suit "recognizes a specific need... and suggests a theoretical answer to that need. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement"). The instant specification does not describe the claimed invention in terms that will "enable any person skilled in the art... to make and use" the invention commensurate in scope with the claims. At most, the specification will enable a person of ordinary skill in the art to attempt to discover how to practice the claimed invention. "(A) specification which describes' does not necessarily also enable' one skilled in the art to make or use the claimed invention." See In re Armbruster, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975). Further, it is unclear how the disclosure of techniques for the expression of 121P1F1 polypeptides in a host cell provides adequate enablement for the 121P1F1 variant of SEQ ID NO:5 in the absence of evidence that the 121P1F1 variant of SEQ ID NO:5 is found to be differentially expressed in cancerous cells relative to corresponding healthy tissue. Further, those of skill in the art recognize that polyclonal antibodies are characterized by non-specific binding and the data of Figure 13, showing the expression of 121P1F1 in various cancer cell lines cannot be extrapolated to the expression of 121P1F1 variants in cancer cells because there is insufficient nexus between the expression of any particular 121P1F1 variant and cancer. The specification does not provide any evidence or nexus between the expression of the 121P1F1 variant of SEQ ID NO:5 and cancer. The specification does not provide sufficient guidance as to which isolated 121P1F1-related protein or any fragment of said protein would share the same function or characteristic(s) (i.e., expression profile) as the 121P1F1 protein of SEQ ID NO:2. Neither does the specification provide any working examples of any 121P1F1-related protein (i.e., SEQ ID NO:5) that have the same functional activities or characteristics, i.e., highly expressed in prostate cancer as the 121P1F1 protein.
The examiner acknowledges applicants remarks regarding the parent gene product of US Patent 6,924,358 andUSSN 11/125,805, however, it is noted that the 121P1F1 variants of USSN 09/799,250, which issued as US Patent 6,924,358 were rejected under enablement and lack of adequate written description under the first paragraph of 35 U.S.C. 112. Further, the examiner notes that none of the 121P1F1 variants issued in the 358 patent and USSN 11/125,805 is not drawn to 121P1F1 variants.
In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the absence of working examples, and the limited amount of direction provided, it would take undue experimentation to practice the claimed invention and the rejection is maintained.

Respectfully,
David J. Blanchard
571-272-0827